

526 Rec'd PCT/PTO 02 JUN 2000

FORM PTO-1390 (REV 12-79-99)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTORNEY'S DOCKET NUMBER 5727-65998
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371			U.S. APPLICATION NO. (If known, see 37 CFR 1.51) Unknown 08/555718
INTERNATIONAL APPLICATION NO. PCT/US98/25850	INTERNATIONAL FILING DATE 04 December 1998	PRIORITY DATE CLAIMED 04 December 1997	
TITLE OF INVENTION INSTRUMENT SETUP UTILITY PROGRAM			
APPLICANT(S) FOR DO/EO/US BATMAN, Carol Jane; BYRD, Nancy Kennedy; DISHOE, Timothy J.; HENDERSON, Les G.; HOPKINSON, Patricia A.			
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:			
<ol style="list-style-type: none">1. <input checked="" type="checkbox"/> This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.2. <input type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.3. <input type="checkbox"/> This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).4. <input type="checkbox"/> A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2))<ol style="list-style-type: none">a. <input checked="" type="checkbox"/> is transmitted herewith (required only if not transmitted by the International Bureau).b. <input type="checkbox"/> has been transmitted by the International Bureau.c. <input checked="" type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).6. <input type="checkbox"/> A translation of the International Application into English (35 U.S.C. 371(c)(2)).7. <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))<ol style="list-style-type: none">a. <input type="checkbox"/> are transmitted herewith (required only if not transmitted by the International Bureau).b. <input type="checkbox"/> have been transmitted by the International Bureau.c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.d. <input checked="" type="checkbox"/> have not been made and will not be made.8. <input type="checkbox"/> A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).10. <input type="checkbox"/> A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).			
Items 11. to 16. below concern document(s) or information included:			
<ol style="list-style-type: none">11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.13. <input checked="" type="checkbox"/> A FIRST preliminary amendment. <input type="checkbox"/> A SECOND or SUBSEQUENT preliminary amendment.14. <input type="checkbox"/> A substitute specification.15. <input type="checkbox"/> A change of power of attorney and/or address letter.16. <input checked="" type="checkbox"/> Other items or information:<ol style="list-style-type: none">a. Copies of Substitute Sheets 1-4 of the PCT Request;b. Copy of Form PCT/IB/306 Regarding DZADO, Michael Daniel;c. Copies of PCT International Search Report and Each Reference Cited Therein;d. Copies of PCT International Preliminary Examination Report and Each Newly Cited Reference Attached Thereto			

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US APPLICATION NO. (if known) (37 CFR 1.55) Unknown		INTERNATIONAL APPLICATION NO. PCT/US98/25850		ATTORNEY'S DOCKET NUMBER 5727-65998	
17. <input checked="" type="checkbox"/> The following fees are submitted: BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)): Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO \$970.00 International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO \$840.00 International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO \$690.00 International preliminary examination fee paid to USPTO (37 CFR 1.482) but all claims did not satisfy provisions of PCT Article 33(1)-(4) \$670.00 International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(1)-(4) \$96.00 ENTER APPROPRIATE BASIC FEE AMOUNT =				CALCULATIONS PTO USE ONLY	
Surcharge of \$130.00 for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(e)).				\$ 130.00	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	84 - 20 =	64	X \$18.00	\$ 1152.00	
Independent claims	1 - 3 =	-0-	X \$78.00	\$ -0-	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$260.00	\$ 260.00	
TOTAL OF ABOVE CALCULATIONS =				\$2232.00	
Reduction of 1/2 for filing by small entity, if applicable. A Small Entity Statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28).				\$ -0-	
SUBTOTAL =				\$ 2232.00	
Processing fee of \$130.00 for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				\$ -0-	
TOTAL NATIONAL FEE =				\$ 2232.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property				\$ -0-	
TOTAL FEES ENCLOSED =				\$ 2232.00	
				Amount to be:	\$
				refunded	
				charged	\$
a. <input checked="" type="checkbox"/> A check in the amount of \$ <u>2232.00</u> to cover the above fees is enclosed.					
b. <input type="checkbox"/> Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees. A duplicate copy of this sheet is enclosed.					
c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>10-0433</u> . A duplicate copy of this sheet is enclosed.					
NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.					
SEND ALL CORRESPONDENCE TO:					
CONARD, Richard D. BARNES & THORNBURG 11 South Meridian Street Indianapolis, IN 46204 US					
SIGNATURE: <i>Richard D. Conard</i>					
NAME Richard D. Conard					
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BARNES & THORNBURG

09555718 09/555718
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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

<i>Group:</i>	Unknown	}
		}
<i>Attorney</i>		}
<i>Docket:</i>	5727-65988	}
		}
<i>Applicant:</i>	BATMAN, Carol Jane; BYRD Nancy	}
	Kennedy; DISHOP, Timothy J.;	}
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	TETZLAFF, Tracy L.; SLY, Lynne	}
	Denise; KLEM, Kurt Gerard	}
		}
<i>Invention:</i>	INSTRUMENT SETUP UTILITY	}
	PROGRAM	}
		}
<i>U.S. Serial No:</i>	Unknown	}
		}
<i>International. Serial No:</i>	PCT/US98/25850	}
		}
<i>International Filing Date:</i>	04 December 1998	}
	(04.12.98)	}
		}
<i>Earliest Priority Date:</i>	04 December 1997	}
	(04.12.97)	}

FIRST PRELIMINARY AMENDMENT

Attention: DO/EO/US
Box PCT
Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Preliminary to the examination of the above-identified national patent application submitted herewith, applicants request entry of the following amendments.

In the Description

After the title, please insert the following paragraph:

--Cross-References to Related Applications

This application is a U.S. national counterpart application of international application serial No. PCT/US98/25850 filed December 4, 1998, which claims priority to U.S. provisional application serial No. 60/067,499 filed December 4, 1997.--

REMARKS

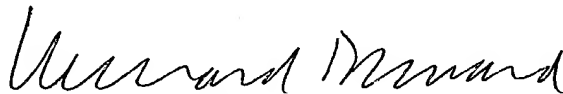
This Preliminary Amendment is being submitted to indicate the relationship of the subject U.S. national application to previously filed applications as required under 37 C.F.R. 1.78.

Claims 1-32 are currently pending in this application.

No amendment is believed to go beyond the disclosure in the international application as originally filed.

The application is believed to be in condition for examination and allowance. Consideration of the claims, leading to their allowance and passage of the application to issuance, is respectfully requested.

Respectfully submitted,



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INSTRUMENT SETUP UTILITY PROGRAM

This is a related application to U.S.S.N. 60/067,512, titled
INSTRUMENT, filed December 4, 1997, U.S.S.N. 60/067,499, filed December 4,
5 1997, titled INSTRUMENT SETUP UTILITY PROGRAM, U.S.S.N.
_____, titled INSTRUMENT, and U.S.S.N. _____, titled
INSTRUMENT, filed on the same date as this application. These related applications
are assigned to the same assignee as this application. The disclosures of those
applications are incorporated herein by reference.

Field of the Invention

This invention relates to a utility program useful in, for example, the
setup of, and communication with, instruments of the general type described in
U.S.S.N. 60/067,512.

Disclosure of the Invention

A method of configuring a hand-held instrument for determining the
concentration of a medically significant component of a body fluid or a control
comprises the steps of providing a configuring computer having a first port for
20 transmitting at least one of instructions and data for configuring the instrument,
providing on the instrument a second port for receiving said at least one of instructions
and data from the configuring computer, coupling said first port to said second port,
transmitting said one of instructions and data to configure said instrument from said
first port, receiving said one of instructions and data at said second port, and
25 configuring said instrument according to said one of instructions and data transmitted
from said first port and received at said second port.

Illustratively according to the invention, the step of providing a
configuring computer having a first port for transmitting at least one of instructions
and data for configuring the instrument comprises the step of providing a configuring
30 computer having a first port for transmitting instructions for configuring the
instrument.

Further illustratively according to the invention, the step of providing a

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configuring computer having a first port for transmitting at least one of instructions and data for configuring the instrument comprises the step of providing a configuring computer having a first port for transmitting data for configuring the instrument.

5 Additionally illustratively according to the invention, the hand-held instrument further comprises a display for displaying information related to the determined concentration. The step of transmitting said one of instructions and data to configure said instrument from said first port comprises the step of transmitting said one of instructions and data from said first port to configure said display.

10 Illustratively according to the invention, the method further comprises the step of transmitting one of instructions and data concerning determined concentration of a medically significant component of a body fluid from the second port to the first port.

15 Further illustratively according to the invention, the step of transmitting one of instructions and data concerning determined concentration of a medically significant component of a body fluid from the second port to the first port comprises the step of transmitting data concerning determined concentration of a medically significant component of a body fluid from the instrument to the computer.

Additionally illustratively according to the invention, the method further comprises updating a file in the computer with the transmitted data.

20 Illustratively according to the invention, the steps of transmitting said one of instructions and data to configure said instrument from said first port and receiving said one of instructions and data at said second port comprise transmitting said one of instructions and data through a fiber optic coupler from said first port to said second port.

25 Further illustratively according to the invention, the instrument comprises an instrument for determining the glucose concentration of blood, a blood fraction or a control.

30 Additionally illustratively according to the invention, the step of transmitting said one of instructions and data concerning determined concentration of a medically significant component of a body fluid from the second port to the first port comprises the step of transmitting said one of instructions and data concerning determined concentration of a medically significant component of a body fluid via a

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modem from the second port to the first port.

Brief Description of the Drawings

The invention may best be understood by referring to the following
 5 detailed descriptions of illustrative embodiments and the accompanying drawings. In
 the drawings:

Fig. 1 illustrates a diagram of a system implementing a utility program
 according to the present invention;

Fig. 2 illustrates installation of a utility program according to the
 10 present invention where the program is distributed on one or more disks containing the
 program in one or more languages; and,

Figs. 3-60 illustrate various screens displayed during the running of a
 utility program according to the invention.

Detailed Descriptions of Illustrative Embodiments

This invention relates to a utility program useful in, for example, the
 setup of, and communication with, instruments of the general type described in
 U.S.S.N. 60/067,512. Fig. 1 illustrates diagrammatically a system implementing the
 utility program 12 of the present invention. Setup of such an instrument 10 is handled
 20 by a portion of the program 12 sometimes referred to hereinafter as a Meter Setup
 Manager through a docking station provided for the instrument 10 on a personal
 computer (PC) 14. Communication between the docked instrument 10 and the PC 14
 is coupled through a serial cable 16 such as, for example, a fiber optic connector, from
 a port 17 on instrument 10 to a port 18 on the PC 14. Communication with a remote
 25 instrument 10', such as for the downloading of test results from storage on board the
 instrument 10' to the PC 14, is handled by a portion of the program sometimes referred
 to hereinafter as a Phone-In Manager. Phone-In Manager is conducted via telephone
 modems 20, 22 at the remote instrument 10' site and the PC 14.

Installation of the program 12, where the program is distributed on one
 30 or more disks containing the program in one or more languages, for example, is
 achieved as illustrated in Fig. 2. The user 24 may be asked to enter certain security
 information, for example, to verify the user 24's access to the PC 14 on which the

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program 12 is loaded. A program 12 screen displays a list of utility languages from which the user 24 selects one. Illustratively, the user 24 will have to reinitialize the program 12 if, after selection of a utility language, the user 24 decides to select a different utility language.

5 Meter Setup Manager

Certain functions of the program can be performed only while an instrument of the general type discussed above is connected through, for example, a serial cable 16 rather than through modems 20, 22 and phone line 23, to the PC 14. A Meter Setup Manager icon, for example, an illustration of the instrument 10, will
 10 appear on one of the early screens. Once the user 24 clicks on the Meter Setup Manager icon, a copyright screen will appear briefly and will be followed by a "Welcome" screen illustrated in Fig. 3. The "Welcome" screen includes a list of tasks the Meter Setup Manager is capable of performing at the user 24's option. This "Welcome" screen can be deselected at the user 24's option. If the user 24 has
 15 deselected this screen, the default task will be initialized. If the user 24 has selected the "Create a Meter Setup" option, a standard Microsoft® Windows® development tool, known as the Wizard™, is launched.

Each screen in the meter setup routine is based on the template illustrated in Fig. 4. As an example of the screens based upon this template, Fig. 5
 20 illustrates the "Enter personal information" screen. This screen displays three fields into which the user 24 is directed to enter information pertinent to the patient whose instrument 10 is being set up. The fields are patient name, patient identification, such as, for example, patient number, patient social security number, and so on, and health care provider computer 14 phone number. The next screen, illustrated in Fig. 6, is the
 25 "Glucose units/glucose ranges" screen. With this screen, the user 24 sets up the patient's instrument 10's glucose upper limit, glucose lower limit, hypoglycemic limit, and units of glucose measurement, for example, millimoles per liter (mmol/L) or milligrams per deciliter (mg/dL). The next screen, illustrated in Fig. 7, prompts the user 24 to set up the patient's instrument 10 for the type(s) of insulin the patient is to
 30 take, for example, REGular, NPH or 90/10, and the dosage increments, for example, tenths of a unit, half units, or whole units.

With the next screen, illustrated with sample data in Fig. 8, the user 24

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is prompted to load into the patient's instrument 10 certain events which the patient is then capable of entering into the patient's diary, which the instrument 10 is equipped to keep. From a library of, for example, 255 events, fifteen are chosen from which the patient may select to enter one in his or her diary with each glucose test result. Some
5 one or more of these may be customized for the patient whose instrument 10 is being set up.

The next screen, illustrated with sample data in Fig. 9, permits the user 24 to load into the patient's instrument 10 schedule control over any twenty-four hour period. A glucose test entry regimen dividing the twenty-four hour day into eight two-
10 to five-hour intervals is the default regimen. This default regimen will be displayed on the screen, and the user 24 will be permitted to edit away from the default settings for the individual patient. Editing is done by clicking on the "Edit" button or by double clicking on any of the time block entries. Once the time block to be edited has been highlighted, its entries are available for edit. The program requires that every minute
15 of the twenty-four hour period be accounted for, and does not permit any minute to be in two different time blocks. As a result, adjusting an entry will typically result in an automatic adjustment of another entry.

Advancing to the next screen, illustrated with sample data in Fig. 10, the information just entered is combined in the "Time block information" screen. The
20 insulin types that were selected in the screen illustrated in Fig. 7 are the ones displayed on the screen illustrated in Fig. 10. If insulin type "None" was selected in connection with the setup illustrated in Fig. 7, no dosage can be selected in connection with the setup illustrated in Fig. 10. If the user 24 does not select an exercise type, he may not enter an exercise duration. The events list contains events which were selected in the
25 events screen. The program does not permit the user 24 to list an event on the screen illustrated in Fig. 10 which was not one of the selected events in Fig. 8.

The screen illustrated in Fig. 11 is the meter setup "Insulin pump profile" screen. This screen contains a schedule list box similar to the time blocks schedule list box illustrated in Fig. 9. The user 24 selects an insulin type, and a start
30 date and time for the insulin pump profile. The profile can contain no less than one time block and no more than twelve. The user 24 can insert or edit a time block from the screen. The user 24 can only delete a time block when the profile contains more

With the next screen, illustrated in Fig. 15, the user 24 selects from among a number, for example, eight, of languages in which instruments 10 can be programmed to display information, a number, for example, four, in which the particular instrument 10 being set up can display information at the patient's option. The "Tip Messages" screen, illustrated in Fig. 16, enables a list control that permits the

user 24 to select a number, for example, ten, of tip messages for display on the instrument 10 being set up. If the user 24 does not want tip messages displayed on the patient's instrument 10, the user 24 may deselect the "Tip Messages Enabled for Meter Setup" box. If this box is not checked, the user 24 must select individual messages
5 which the user 24 wants to appear on the patient's instrument 10 at appropriate times.

The user 24 may add custom tip messages to an instrument 10 being set up for a patient. To do this, the user 24 selects the "Custom" button. The screen illustrated in Fig. 17 is displayed. If the user 24 then selects the "Add" button, the screen illustrated in Fig. 18 is displayed. If the user 24 selects the "Edit" button, the
10 screen illustrated in Fig. 19 is displayed. If the user 24 selects the "Remove" button, the tip message highlighted in the screen illustrated in Fig. 17 is deleted. Once these screens have been completed, the instrument 10 setup is complete. The user 24 is presented with a dialog and given instructions on how to view and save the completed setup. This screen is illustrated in Fig. 20.

15 Returning briefly to Fig. 3, if the user 24 selects the "Retrieve an Existing Meter Setup from a Meter" option, and no instrument 10 is connected to the PC 14, the user 24 is asked to connect the instrument 10 to the PC 14. If the user 24 selects "OK" and no instrument 10 is yet connected to the PC 14, the user 24 is again asked to connect the instrument 10 to the PC 14. If the user 24 selects "Cancel," the
20 "Welcome" screen of Fig. 3 again appears. If the user 24 selects "Help," the help facility is launched with troubleshooting information regarding connecting an instrument 10 to the PC 14. If the user 24 selects the "Open an Existing Meter Setup File" from the "Welcome" screen, a Microsoft® Windows® file opening common dialog is launched. The user 24 may then select an instrument 10 setup file to edit or
25 cancel back to the "Welcome" screen.

If the user 24 has selected either the "Open an Existing Meter Setup File" option or the "Retrieve an Existing Meter Setup from a Meter" option, ultimately a summary screen of the general configuration illustrated in Fig. 21 will be displayed. This screen displays the instrument 10 setup. The user 24 may edit this setup by
30 selecting the highlighted text on the screen. The user 24 is then presented with the appropriate instrument 10 setup tab to edit instrument 10 setup options. The basic elements of the summary screen as they appear on the Microsoft® Windows® 95

platform are illustrated in Fig. 21. The title bar contains a descriptor for the data contained in the client area followed by the name of the software. This descriptor may be "New Meter," a filename, or a designation such as "John Smith's Meter." Below the title bar is a menu bar. The menu bar is described later.

5 Below the menu bar, in the client area of the window, is a summary screen. This summary screen contains the current instrument 10 setup settings. The user 24 may edit the information contained on this screen by clicking on the underlined text. This activates the instrument 10 setup tabs, similarly to the screen illustrated in Fig. 22, "Instrument setup manager-tab template screen." The tab control contains
10 screens that are nearly identical to the ones available via the instrument 10 setup Wizard™, with the difference being that the Wizard™ provides a simple, step-by-step approach to entering data, whereas the tab control gives the user 24 one-click access to any screen. The tabs can also be used to set up instruments 10. They provide a somewhat more powerful tool for doing this. However, it is suggested that, for the
15 first few times at least, the user 24 perform instrument 10 setup using the Wizard™ as a learning tool.

 With reference to Fig. 23, the contents of the "Personal" tab are illustrated. As will be appreciated, the contents of this tab, and the appropriate user 24 interactions, are generally as described in connection with the screen illustrated in Fig.
20 5. Referring to Fig. 24, the contents of the "Glucose units/ranges" tab and the appropriate user interactions are generally as described in connection with the screen illustrated in Fig. 6. Turning to Fig. 25, the contents of the "Insulin type" tab are illustrated. These contents and the associated user 24 interactions are generally as described in connection with the screen illustrated in Fig. 7. Referring to Fig. 26, the
25 contents of the "Event markers" tab and the related user 24 interactions are generally as described in connection with the screen illustrated in Fig. 8.

 Turning to Fig. 27, the contents of the "Time blocks" tab are illustrated. These contents and the associated user 24 interactions are generally as described in connection with the screen illustrated in Fig. 9. With reference to Fig. 28, the contents
30 of the "Time blocks" tab and user 24 interactions are generally as described in connection with the screen illustrated in Fig. 10. Referring to Fig. 29, the contents of the "Insulin pump profile" tab and the related user 24 interactions are generally as

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5 associated with it are generally as described in connection with the screen illustrated in Fig. 15. Referring to Fig. 32, the contents of the “Tip messages” tab and user 24 interactions associated with it are generally as described in connection with the screen illustrated in Fig. 16.

open the help facility and obtain context sensitive help. All dialogs also have associated help buttons which access the help facility. The instrument 10 setup manager also has a help menu. The user 24 may cancel from the "Welcome" screen by selecting the "Cancel" button on that screen. When that action is taken, the welcome dialog box illustrated in Fig. 3 is dismissed and the main screen is displayed.

The user may select “Retrieve Patient Data from a Meter” connected to the computer 14 from the “Welcome” screen. If the user 24 then selects “OK,” a sequence to retrieve patient data from a connected instrument 10 is initiated. This is exactly equivalent to selecting the “Retrieve Patient Data” option from the Meter menu. The Meter Setup Manager functions are divided into “File,” “Meter,” “View” and “Help” menus. See, for example, Fig. 21. The options under the “File” menu include “New,” “Open . . . ,” “Close,” “Save,” “Save As . . . ,” “Print,” “View Patient Report . . . ,” “Print Patient Report . . . ,” “Edit Patient Database . . . ,” “Recent File List” and “Exit.” The options under the “Meter” menu include “Retrieve Patient Data,” “Retrieve Meter Setup,” “Send Meter Setup,” “Clear Patient Diary” and “COMmunication Port Settings” The options under the “View” menu include “Toolbar,” “Status Bar” and “Options” The options under the “Help” menu include “Help topics” and “About”

new instrument 10 setup with the Meter Setup Wizard. The user 24 may change this setting to Meter Setup Tabs by selecting “Options” under the “View” menu. If there is any unsaved data in the fields, the user 24 is prompted to save it. “Open” prompts the

user 24 to name a file to open and opens a Meter Setup File. If the selected file is not an instrument 10 setup file, an error message is displayed and the Summary Screen is blank. If the selected file is an instrument 10 setup file, then the data is initially displayed with the Summary Screen. The user 24 may edit the open document with the Meter Setup Tabs by clicking on the underlined text, or may edit the open document with the Meter Setup Wizard™ by selecting the Wizard™ toolbar button.

“Close” closes the currently open instrument 10 setup file. If the currently open instrument 10 setup file has not been saved, the user 24 will be prompted to save it. “Save” saves the currently open file. If the file has not yet been assigned a name, the user 24 will be prompted to assign it a name and location. “Save As” saves the current file under the assigned name. The user 24 is prompted to assign it a name and location. “Print” prints the current instrument 10 setup data. “View Patient Report . . .” prompts the user 24 to identify a patient data file to view using the patient name, instrument 10 serial number and the date received or the actual file name to select the file for viewing. “View Patient Report . . .” causes the selected report to be displayed in the format specified by the user 24. See Fig. 33. The user 24 selects the report format by selecting “Options” from the “View” menu. “View Patient Report Browser,” Fig. 34, is accessed by the user 24 clicking on the “Browse . . .” button on the screen illustrated in Fig. 33. “View Patient Report Browser” permits the user 24 to scroll through the patient reports saved in the database for one the user wishes to view. “Print Patient Report . . .” causes the selected report to be printed. The user 24 selects the report to be printed in response to a prompt from this routine. See Fig. 35. “Print Patient Report Browser,” Fig. 36, is accessed by the user 24 clicking on the “Browse . . .” button on the screen illustrated in Fig. 35. “Print Patient Report Browser” permits the user 24 to scroll through the patient reports saved in the database for one the user 24 wishes to print. “Edit Patient Database . . .” permits the user 24 to add, delete and edit patient name-to-instrument 10 serial number associations. See Figs. 37 and 38. “Recent File List” causes the four most recently opened files from the Patient Data and Meter Setup databases to be displayed, and permits the user 24 to open one of these files by selecting it from the list. “Exit” causes the computer 14 to exit from the Meter Setup Manager routine.

The “Meter” menu contains commands that act upon the instrument 10

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that is connected to the computer 14. "Retrieve Patient Data" prompts the user 24 to enter a filename and a location to save the patient data to, and then retrieves the patient data from the instrument 10 connected to the computer 14. If no instrument 10 is connected to the computer 14, the user 24 is prompted to connect one. Once the data transfer is complete, the patient data is displayed in the format selected by the user 24. An "Options" screen illustrated in Fig. 39 permits the user 24 to select various Meter Setup Manager application options. For example, under the "Report settings" tab, the user 24 is prompted to select from among the various report formats: "Diary," "Glucose values," Trend," "Glucose graph," "Average trend," Glucose ranges," and "Hypoglycemic events." The user 24 is also prompted to select the time range for average trend, glucose ranges and hypoglycemic events reports. The user 24 is further prompted to select the glucose units, for example, mg/dL or mmol/L, for the reports. Under the "New meter setup" tab, the user 24 is prompted to select how new instrument 10 setup will be performed, permitting the user 24 to select the Meter Setup Wizard™, or use the tabs, or instructing the Meter Setup Manager always to ask how instrument 10 setup is to be performed. See Fig. 40 and the discussion of Fig. 22 above. Under the "Meter COM port" tab, the user 24 is prompted to select the computer 14 port 18 through which communication with the instrument 10 will be conducted. See Fig. 41. Referring to Fig. 42, under the "Startup" tab, the user 24 is prompted to indicate whether the "Welcome" screen, Fig. 3, should be displayed at startup.

"Retrieve Meter Setup" retrieves the Meter Setup Data from an instrument 10 and displays the instrument 10 setup data using the Summary Screen. If no instrument 10 is connected to the computer 14, the user 24 is prompted to connect one. Fig. 43 illustrates the screen which is displayed when instrument 10 setup status data is being transferred. When the instrument 10 setup data transfer is complete, if the instrument 10 serial number does not have associated with it a patient name, the "Enter Patient Name" prompt appears, Fig. 44, prompting the user 24 to enter the patient's name. The entered patient's name then appears on the summary screen.

"Send Meter Setup" sends instrument 10 setup data to an instrument 10 connected to the computer 14. If no instrument 10 is connected to the computer 14, the user 24 will be prompted to connect one. Before the instrument 10 setup data is

sent to the instrument 10, the user 24 is prompted to set the date and time on the instrument 10. The user 24 has the option of not changing the instrument 10's date and time, synchronizing the instrument 10's date and time to the computer 14's or manually setting the instrument 10's date and time. See Fig. 45. As the instrument 10
5 setup data is being sent to the instrument 10, the screen illustrated in Fig. 46 is displayed.

"Clear Patient Diary" clears the patient diary data of an instrument 10 connected to the computer 14. To prevent accidental clearing of diary, the user 24 is prompted to save patient data to files before proceeding with clearing of patient diary
10 from an instrument 10. If no instrument 10 is connected to the computer 14, the user 24 will be prompted to connect one. "COM Port Settings" causes the screen illustrated in Fig. 47 to be displayed. The user 24 is prompted to select the computer 14 port 18 through which communication with the instrument 10 will be conducted.

The "View" menu contains items that adjust the settings for the Meter
15 Setup Manager. The "Toolbar" command permits the user 24 to select whether the toolbar is displayed. The "Status Bar" command permits the user 24 to select whether the status bar, which is located at the bottom of the Meter Setup Manager application screen, is displayed. "Options" creates a display which permits the user 24 to choose various Meter Setup Manager application options. This multi-page display is
20 illustrated in Figs. 48-51. See the above discussion of Figs. 39-42.

The "Help" menu contains items that provide the user 24 with access to information about the Meter Setup Manager. "Help Topics" displays the table of contents of a help file. The user 24 may navigate via hyperlinks from the table of contents to the contents of the various help file entries. The "About" entry causes the
25 version of the software and copyright notice information to be displayed.

The toolbar for the Meter Setup Manager contains command buttons for commonly accessed features, such as "File-New," "File-Open," "File-Save," "File-Print," "Meter Setup Wizard," "Meter Communication-Retrieve Meter Setup," "Meter Communication-Send Meter Setup" and "Meter Communication-Retrieve Patient
30 Data."

Phone-In Manager

All functions related to telephone modem 20, 22-based communication

between a patient's instrument 10' and the user 24's computer 14 fall within the control of the Phone-In Manager routine. Consequently, the Phone-In Manager routine illustratively runs all of the time. Installation of the utility program 12 places a link to the Phone-In Manager routine's executable in the Microsoft® Windows® startup folder, so that the Phone-In Manager routine launches automatically whenever Microsoft® Windows® launches. In rare cases, the user 24 may need to launch the Phone-In Manager routine by double clicking on its icon, for example, an illustration of a telephone, or by other Microsoft® Windows® convention.

After the Phone-In Manager routine is launched, a copyright screen will appear briefly. After launch, Phone-In Manager is generally minimized. This waiting state is generally referred to herein as "Wait for New Calls." The user 24 may also "Review Calls" or "Perform Administrative Tasks." From the perspective of a patient who is using an instrument 10', the patient's data may be sent to the health care professional's office prior to a scheduled appointment. The patient may also phone the patient data in to the health care professional's office at any time, as necessary, to permit the health care professional to review it. From the perspective of the health care professional, such a connection is completely automatic. The patient performs all necessary interactions to achieve the data transfer.

As previously noted, Phone-In Manager is always running, at least as a background task. It will be active only when a phone call comes in to the health care professional's office computer 14 or when a user 24 restores it to display status on the computer 14 monitor. A user 24 restores Phone-In Manager, for example, to review calls or to change any of the Phone-In Manager configuration options. Fig. 52 illustrates the Phone-In Manager main screen restored. When patients phone their data in via modems 20, 22 to the health care professional's computer 14, the Phone-In Manager keeps track of each call and the data that was received.

All calls are logged in order from most recent to oldest. Each logged call is displayed in the list with the instrument 10' serial number, patient's name if available, and the time and date of the phone call. The user 24 of the computer 14 may view or print patient data by highlighting the desired patient's instrument 10' serial number and selecting the "View" or "Print" button, respectively. The user 24 may also select the "Auto Print" option, in which case incoming patient data is automatically

printed. The user 24 may also view or print patient data which has expired from the Recent Calls list displayed in the screen illustrated in Fig. 52. Selecting the "View" button results in the display of the selected patient's data in the format illustrated in Fig. 53. The user 24 can then choose to print or close this file. The user 24 can also

5 view this screen by selecting old files to view from the menu. The files can be selected by the serial number of the instrument 10', patient name and data transfer date, or by file name. Selecting the "Print" button results in the printing of the selected patient's data in the report format illustrated in Fig. 53. The user 24 can also print files which have expired from the Recent Calls list by selecting old files to print from the menu.

10 Again, the files to be printed can be selected by the serial number of the instrument 10', patient name and data transfer date, or by file name. If the "Auto Print" check box is checked, patient reports will be printed upon receipt.

In Phone-In Manager as in Meter Setup Manager, features that are accessed on a routine basis are located in the client area of the window. These

15 features and their data are easily accessible and reviewable. Other features which are used less frequently are located in a standard Microsoft® Windows® menu bar. These include the "File," "View" and "Help" menus. The "File" menu contains commands which operate on patient data. "View Patient Reports" permits the user 24 to view older patient files by selecting the instrument 10' serial number, patient name and date

20 of receipt of data, or the actual file name. "Print Patient Reports" permits the user 24 to print older patient files by selecting the instrument 10' serial number, patient name and date of receipt of data, or the actual file name. "Edit Patient Database" permits the user 24 to add, delete and edit patient name to instrument 10' serial number associations. "Print Setup" is the standard Microsoft® Windows® printer 30 setup

25 routine. "Exit" results in the Phone-In Manager routine being exited.

The "View" menu contains menu items that permit the user 24 to view and modify various Phone-In Manager data stores. The "Status Bar" permits the user 24 to turn the status bar at the bottom of the main window on or off. "Phone Line Status" displays a dialog, illustrated in Fig. 54, containing the states of all phone lines.

30 This permits the user 24 to enable or disable one or more of the phone lines 23 connected to the computer 14. When the utility program 12 is running in Windows® 95 and the user 24 clicks on the "Add" button or the "Properties" button on the screen

The “Help” menu contains items that provide the user 24 with access to information about the Phone-In Manager. “Help Topics” displays the table of contents of a help file. The user 24 may navigate via hyperlinks from the table of contents to the contents of the various help file entries. The “About” entry causes the version of the utility program 12 and copyright notice information to be displayed.

CLAIMS:

1. A method of configuring a hand-held instrument for determining the concentration of a medically significant component of a body fluid or a control, the method comprising the steps of providing a configuring computer having a first port for transmitting at least one of instructions and data for configuring the instrument, providing on the instrument a second port for receiving said at least one of instructions and data from the configuring computer, coupling said first port to said second port, transmitting said one of instructions and data to configure said instrument from said first port, receiving said one of instructions and data at said second port, and configuring said instrument according to said one of instructions and data transmitted from said first port and received at said second port.

2. The method of claim 1 wherein the step of providing a configuring computer having a first port for transmitting at least one of instructions and data for configuring the instrument comprises the step of providing a configuring computer having a first port for transmitting instructions for configuring the instrument.

3. The method of claim 2 wherein the step of providing a configuring computer having a first port for transmitting at least one of instructions and data for configuring the instrument comprises the step of providing a configuring computer having a first port for transmitting data for configuring the instrument.

4. The method of claim 1 wherein the step of providing a configuring computer having a first port for transmitting at least one of instructions and data for configuring the instrument comprises the step of providing a configuring computer having a first port for transmitting data for configuring the instrument.

5. The method of claim 1 wherein the hand-held instrument further comprises a display for displaying information related to the determined concentration, the step of transmitting said one of instructions and data to configure said instrument from said first port comprising the step of transmitting said one of instructions and data from said first port to configure said display.

6. The method of claim 2 wherein the hand-held instrument further comprises a display for displaying information related to the determined concentration,

15. The method of claim 14 wherein the step of transmitting one of instructions and data concerning determined concentration of a medically significant

24. The method of claim 23 wherein the step of transmitting one of
30 instructions and data concerning determined concentration of a medically significant
component of a body fluid from the second port to the first port comprises the step of
transmitting data concerning determined concentration of a medically significant

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component of a body fluid from the instrument to the computer.

25. The method of claim 24 and further comprising updating a file in the computer with the transmitted data.

26. The method of claim 7 further comprising the step of
5 transmitting one of instructions and data concerning determined concentration of a medically significant component of a body fluid from the second port to the first port.

27. The method of claim 26 wherein the step of transmitting one of instructions and data concerning determined concentration of a medically significant component of a body fluid from the second port to the first port comprises the step of
10 transmitting data concerning determined concentration of a medically significant component of a body fluid from the instrument to the computer.

28. The method of claim 27 and further comprising updating a file in the computer with the transmitted data.

29. The method of claim 1, 2, 3, 4, 5, 6 or 7 wherein the steps of
15 transmitting said one of instructions and data to configure said instrument from said first port and receiving said one of instructions and data at said second port comprise transmitting said one of instructions and data through a fiber optic coupler from said first port to said second port.

30. The method of claim 29 wherein the instrument comprises an
20 instrument for determining the glucose concentration of blood, a blood fraction or a control.

31. The method of claim 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19,
20, 21, 22, 23, 24, 25, 26, 27 or 28 wherein the step of transmitting said one of instructions and data concerning determined concentration of a medically significant
25 component of a body fluid from the second port to the first port comprises the step of transmitting said one of instructions and data concerning determined concentration of a medically significant component of a body fluid via a modem from the second port to the first port.

32. The method of claim 31 wherein the instrument comprises an
30 instrument for determining the glucose concentration of blood, a blood fraction or a control.

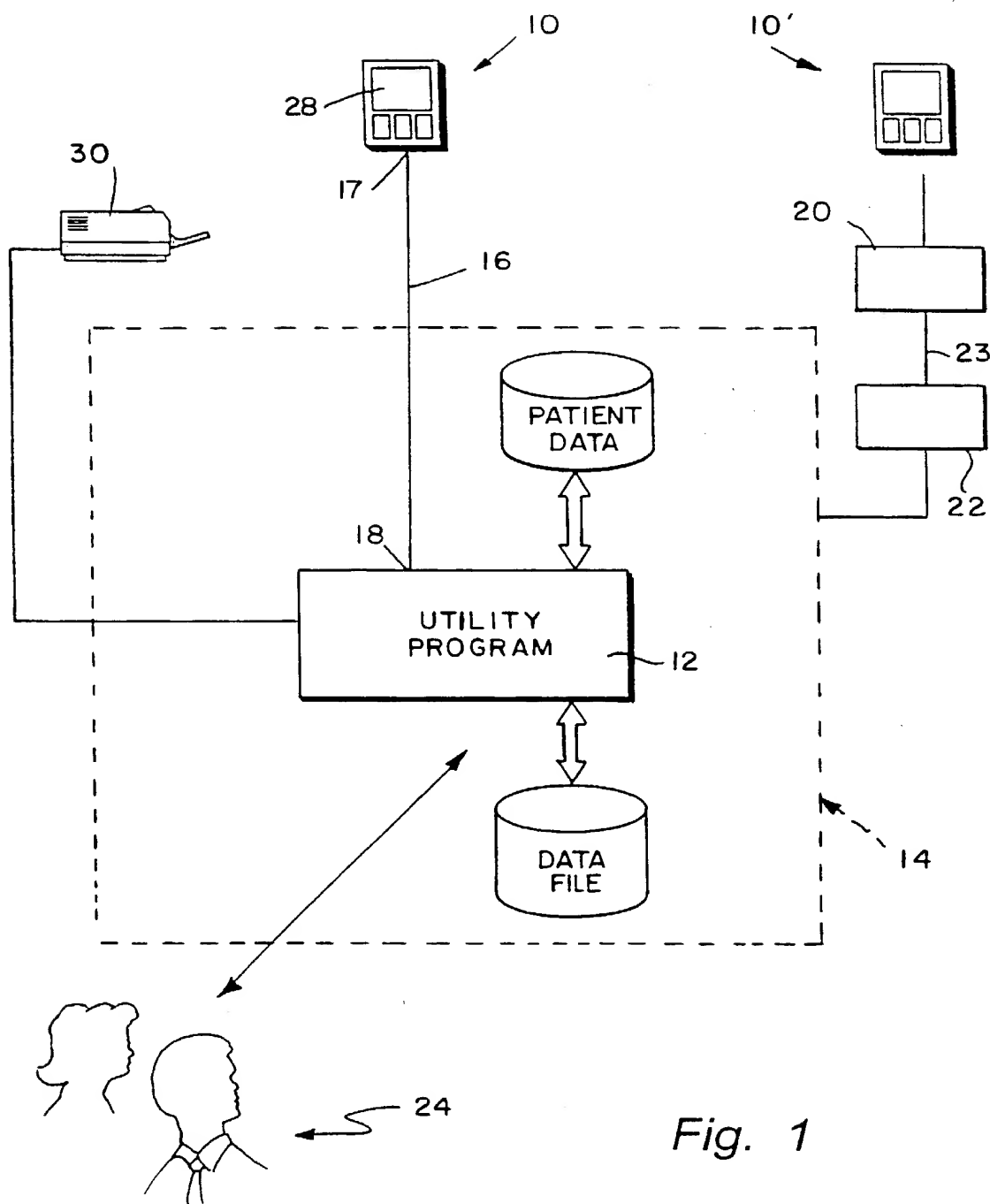
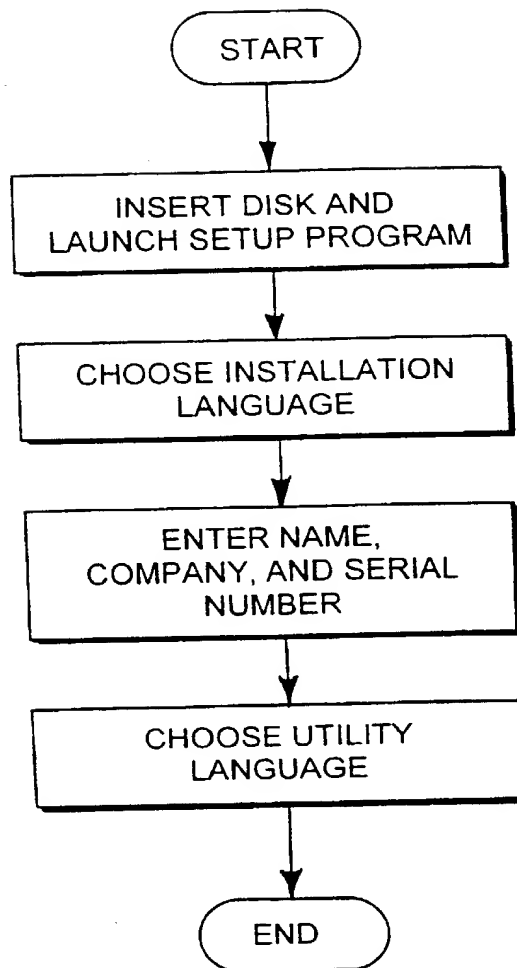
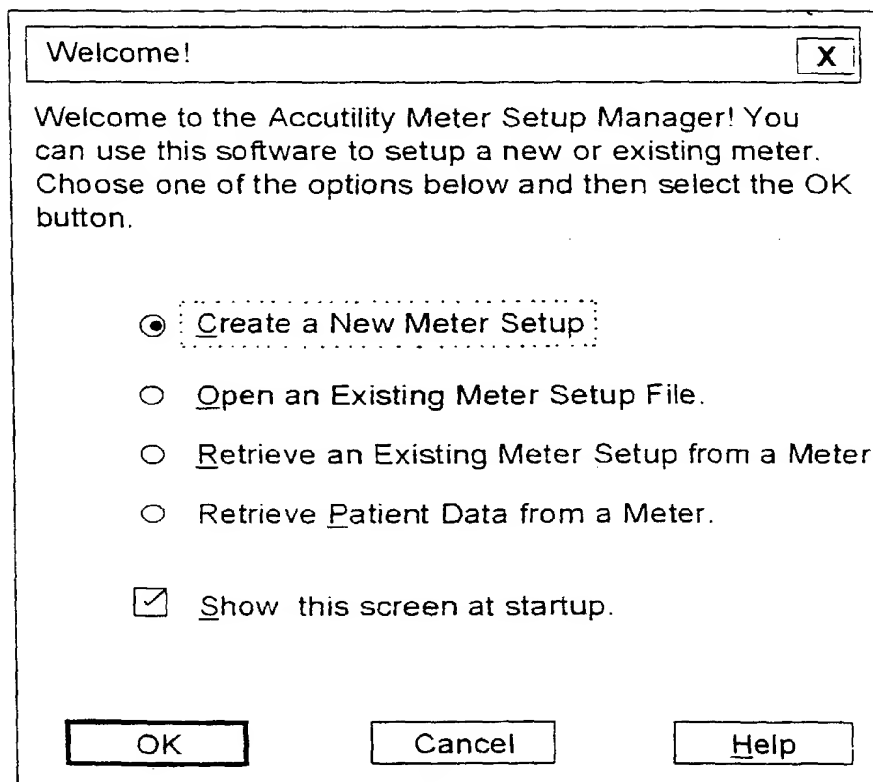


Fig. 1

*Fig. 2*

*Fig. 3*

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Fig. 4

Meter Setup Wizard -

Instructions on what to do on each screen appear here.

Interaction

< Back Next > Cancel Help

Fig. 5

Meter Setup Wizard - Personal Information

Enter the Patient and Healthcare Provider Information below.

The Patient ID may be a number or a name that is up to 20 characters in length.

Patient Information

Name:

ID:

Healthcare Provider Information:

Healthcare Computer Phone Number:

< Back Next > Cancel Help

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Fig. 6

Meter Setup Wizard - Glucose Units/Ranges

Units of Measure

Glucose: ☒ mg/dL ☐ mmol/L

Glucose Limits

Upper Limit: mg/dL

Lower Limit: mg/dL

Hypo: mg/dL

< Back **Next >** Cancel Help

Fig. 7

Meter Setup Wizard - Insulin Type

Select up to three Insulin Types. These will be the only types available in the meter.

Check the Insulin Logging box if you want to record insulin information in your meter.

☐ Insulin Logging Enabled for Meter Setup

Insulin Types

Insulin Type 1: Insulin Type 2: Insulin Type 3:

Insulin Increment:

☒ Tenth Unit ☐ Half Unit ☐ Whole Unit

< Back **Next >** Cancel Help

Meter Setup Wizard - Event Markers

Select up to 15 Event Markers to add to the Meter Setup. The Events will appear in the meter in the order they appear in the 'Events To Load Into Meter' list.

You have selected 15 Events

S	Available Events	Events to Load into Meter
	Active	Before Meal
	After Breakfast	After Meal
	After Dinner	Fasting
	After Exercise	Snack
	After Lunch	Feel Hypo.
	After Meal	Before Exercise
	Bed Time	After Exercise
	Before Breakfast	Illness
	Before Dinner	Invalid Test
	Before Exercise	Other's Result
	Before Lunch	User Defined
	Before Meal	Stress
	Cold Outdoors	L1 Control
	Different Food	L2 Control
	Drank Alcohol	Oral Medication

S = Selected Event Markers

Meter Setup Wizard - Time Blocks

Time Block information is contained in the list below.

The minimum time span for a Time Block is 1/2 hour. Editing the start time of a Time Block automatically adjusts the end time of the previous Time Block. No time gaps are allowed between Time Blocks.

To edit an existing Time Block, select the Time Block and press the Edit button, or double click on the Time Block entry in the list.

Time Block Name	3 Letter Name	Start Time	End Time	Duration
Breakfast	Brk	6:00 AM	8:59 AM	3.0
Midmorning	Mmo	9:00 AM	11:59 AM	3.0
Lunch	Lun	12:00 PM	2:59 PM	3.0
Midafternoon	Maf	3:00 PM	5:59 PM	3.0
Dinner	Din	6:00 PM	7:59 PM	2.0
Evening	Eve	8:00 PM	9:59 PM	2.0
Bed time	Bed	10:00 PM	2:59 AM	5.0
Night time	Ngt	3:00 AM	5:59 AM	3.0

Add >

< Remove

Edit...

< Back

Next >

Cancel

Help

Fig. 8

Fig. 9

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Fig. 10

Time Block Information [X]

Three Letter Name: Brk

Start time: 6:00 AM [▲▼] End Time: 8:59 AM

Customize Time Block

Insulin Type 1: <None> Dose 0.0

Insulin Type 2: <None> Dose 0.0

Insulin Type 3: <None> Dose 0.0

Exercise Type: <None> [▼] Duration: 0.00 [▲▼]

Carbohydrates: 0 grams

Event 1: No Event [▼] Event 3: No Event [▼]

Event 2: No Event [▼] Event 4: No Event [▼]

[OK] [Cancel] [Help]

Fig. 11

Meter Setup Wizard - Insulin Pump Profile

Check the Insulin Pump Logging box is you want to record Insulin Pump Information in your meter:

☐ Insulin Pump Logging Enabled in Meter Setup

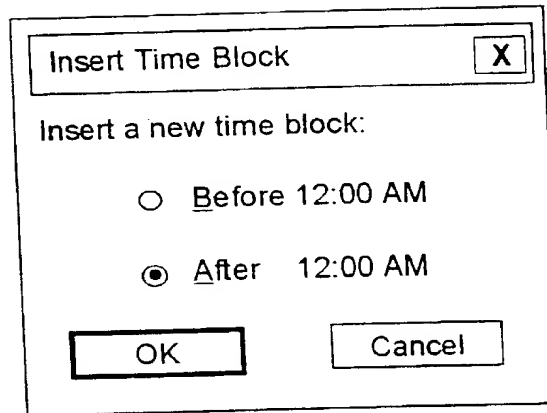
Type of Insulin: <None> [▼]

Profile Start Date: 11/09/98 [▲▼] Profile Start Time: 2:50 PM [▲▼]

Time Block Name	Start Time	End Time	Pump Rate
Time Block #1	12:00 AM	11:59 PM	0.0

[Insert] [Edit...] [Delete]

[< Back] [Next >] [Cancel] [Help]



Insert Time Block [X]

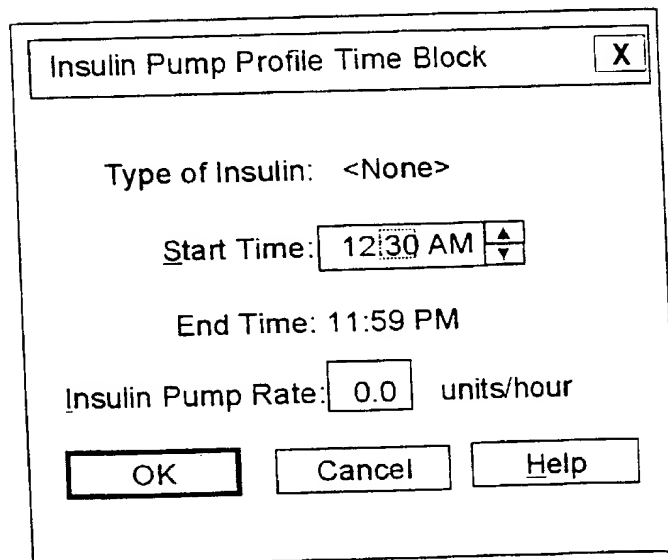
Insert a new time block:

☐ Before 12:00 AM

☒ After 12:00 AM

[OK] [Cancel]

Fig. 12



Insulin Pump Profile Time Block [X]

Type of Insulin: <None>

Start Time: 12:30 AM [▲] [▼]

End Time: 11:59 PM

Insulin Pump Rate: 0.0 units/hour

[OK] [Cancel] [Help]

Fig. 13

Fig. 14

Meter Setup Wizard - Misc. Options

Select the appropriate Meter Customization Options

Decimal Format ☐ Comma [,] ☒ Period [.]

Time Format ☐ 24 Hour ☒ 12 Hour

Date Format ☐ dd-mm-yy ☒ mm-dd-yy

Meter Back Light ☐ Off ☒ On

Beeper ☐ Off ☒ On

< Back Next > Cancel Help

Fig. 15

Meter Setup Wizard - Languages

Select four Languages for the Meter Setup.

Languages

☐ Dutch

☒ English

☒ French

☒ German

☐ Italian

☒ Spanish

☐ Swedish

< Back Next > Cancel Help

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Fig. 16

Meter Setup Wizard - Tip Messages

Select 10 Tip Messages to add to the Meter Setup from the list below.

To add Custom Tip Messages to the list below, select the 'Custom' button

☒ Tip Messages Enabled for Meter Setup

You have selected 10 Tip Messages.

S	C	Available Tip Messages
✓		Check your feet daily
✓		Choose a nutrition goal you can already do
✓		Choose an exercise goal you can already do
✓		Exercise helps keep your blood sugars in range
✓		Exercise is important for good diabetes management
✓		Exercise makes you more fit
		Ketones provide you with important information
		See your dentist every six months
✓		See your diabetes educator regularly
✓		See your doctor regularly
✓		See your eye doctor annually
✓		Tailor goals to fit your own lifestyle

S = Selected Tip Messages
C = Custom Tip Messages

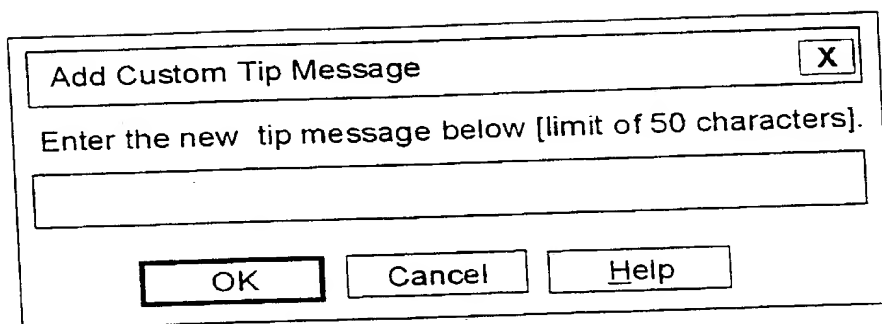
Fig. 17

Custom Tip Messages [X]

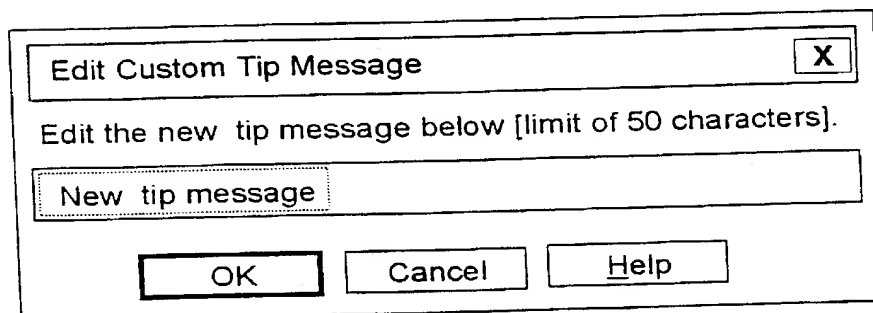
Custom Tip Messages List:

new tip message
new tip message ddd

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A dialog box titled "Add Custom Tip Message" with a close button (X) in the top right corner. Below the title bar, the text "Enter the new tip message below [limit of 50 characters]." is displayed. Underneath this text is a single-line text input field. At the bottom of the dialog box are three buttons: "OK", "Cancel", and "Help".

Fig. 18

A dialog box titled "Edit Custom Tip Message" with a close button (X) in the top right corner. Below the title bar, the text "Edit the new tip message below [limit of 50 characters]." is displayed. Underneath this text is a text input field containing the text "New tip message". At the bottom of the dialog box are three buttons: "OK", "Cancel", and "Help".

Fig. 19

Meter Setup Wizard - Complete Meter Setup

You have finished selecting the Meter Options.

Select the "Finish" button to view the options selected.

To save the options selected [after viewing]:

From the File menu select 'Save' to save to a file.

From the Meter menu, select 'Send Meter Setup' to send the options to a meter that is connected to the computer.

< Back **Finish** Cancel Help

Fig. 20

-Accutivity Meter Setup Manager

File Meter View Help

Summary of Meter Setup
(Select underlined text to make changes)

Personal:

Patient Name	John Smith
Patient ID	<u>default</u>
Healthcare Computer	
Phone Number	<u>default</u>

Glucose Units/Ranges:

Units of Measure	mg/dL
Upper Limit	<u>0</u>
Lower Limit	<u>0</u>
Hypo	<u>0</u>

Insulin Type:

Insulin Logging	Disabled
Insulin Type 1	< <u>None</u> >
Insulin Type 2	< <u>None</u> >
Insulin Type 3	< <u>None</u> >
Insulin Increments	0.1 units

Event Markers:

Before Meal	
After Meal	
Fasting	

For Help, press F1

NUM

Fig. 21

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Fig. 22

A screenshot of a software window with a title bar containing a close button (X). Below the title bar is a row of eight tabs labeled Tab 1 through Tab 8. The main area of the window contains the text "Instructions on what to do on each screen appear here." followed by "Interaction" and a large empty rectangular box. At the bottom of the window are four buttons: OK, Cancel, Apply, and Help.

Fig. 23

A screenshot of a software window titled "Accutivity Meter Setup Manager" with a close button (X). The window has a series of tabs: "Time Block", "Insulin Pump Profile", "Misc Options", "Language", "Tip Messages", "Personal", "Glucose Units/Ranges", "Insulin Type", and "Event Markers". The "Personal" tab is selected. The main area contains the text "Enter the Patient and Healthcare Provider Information below." followed by "The Patient ID may be a number or a name that is up to 20 characters in length." Below this is a section titled "Patient Information" with two input fields: "Name:" containing "John Smith" and "ID:" containing "default". Below that is a section titled "Healthcare Provider Information:" with two input fields: "Healthcare Computer" and "Phone Number:", both containing "default". At the bottom of the window are three buttons: OK, Cancel, and Help.

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Fig. 24

Accutivity Meter Setup Manager X

Time Block | Insulin Pump Profile | Misc Options | Language | Tip Messages

Personal | Glucose Units/Ranges | Insulin Type | Event Markers

Units of Measure

Glucose: ☒ mg/dL ☐ mmol/L

Glucose Limits

Upper Limit: mg/dL

Lower Limit: mg/dL

Hypo: mg/dL

OK Cancel Help

Fig. 25

Accutivity Meter Setup Manager X

Time Block | Insulin Pump Profile | Misc Options | Language | Tip Messages

Personal | Glucose Units/Ranges | Insulin Type | Event Markers

Select up to three Insulin Types. These will be the only types available in the meter.

Check the Insulin Logging box if you want to record insulin information in your meter.

☐ Insulin Logging Enabled for Meter Setup

Insulin Types

Insulin Type 1: Insulin Type 2: Insulin Type 3:

Insulin Increment:

☒ Tenth Unit ☐ Half Unit ☐ Whole Unit

OK Cancel Help

Accutivity Meter Setup Manager X

Time Block Insulin Pump Profile Misc Options Language Tip Messages

Personal Glucose Units/Ranges Insulin Type Event Markers

Select up to 15 Event Markers to add to the Meter Setup

The Events will appear in the meter in the order they appear in the 'Events To Load Into Meter' list.

You have selected 15 Events

S	Available Events ▲		Events to Load into Meter
	Active		Before Meal
	After Breakfast		After Meal
	After Dinner		Fasting
✓	After Exercise	Add >	Snack
	After Lunch		Feel Hypo.
✓	After Meal	< Remove	Before Exercise
	Bed Time		After Exercise
	Before Brekfast		Illness
	Before Dinner		Invalid Test
✓	Before Exercise		Other's Result
	Before Lunch		User Defined
✓	Before Meal		Stress
	Cold Outdoors		L1 Control
	Different Food		L2 Control
	Drank Alcohol ▼		Oral Medication

S = Selected Event Markers

OK Cancel Help

Fig. 26

Accutivity Meter Setup Manager X

Time Block information is contained in the list below.

The minimum time span for a Time Block is 1/2 hour.
 Editing the start time of a Time Block automatically
 adjusts the end time of the previous Time Block. No
 Time gaps are allowed between Time Blocks.

To edit an existing Time Block, select the Time Block and
 press the Edit button, or double click on the Time Block
 entry in the list.

Time Block Name	3 Letter Name	Start Time	End Time	Duration
Breakfast	Brk	6:00 AM	8:59 AM	3.0
Midmorning	Mmo	9:00 AM	11:59 AM	3.0
Lunch	Lun	12:00 PM	2:59 PM	3.0
Midafternoon	Maf	3:00 PM	5:59 PM	3.0
Dinner	Din	6:00 PM	7:59 PM	2.0
Evening	Eve	8:00 PM	9:59 PM	2.0
Bed time	Bed	10:00 PM	2:59 AM	5.0
Night time	Ngt	3:00 AM	5:59 AM	3.0

Fig. 27

Time Block Information X

Three Letter Name: Brk

Start time: 6:00 AM ▲▼ End Time: 8:59 AM

Customize Time Block

Insulin Type 1: <None>	Dose	0.0
Insulin Type 2: <None>	Dose	0.0
Insulin Type 3: <None>	Dose	0.0

Exercise Type: <None> ▼ Duration: 0:00 ▲▼

Carbohydrates: 0 grams

Event 1: No Event ▼ Event 3: No Event ▼

Event 2: No Event ▼ Event 4: No Event ▼

OK Cancel Help

Fig. 28

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Accutivity Meter Setup Manager [X]

Personal | Glucose Units/Ranges | Insulin Type | Event Markers
Time Block | Insulin Pump Profile | Misc Options | Language | Tip Messages

Check the Insulin Pump Logging box is you want to record Insulin Pump Information in your meter:

☒ Insulin Pump Logging Enabled in Meter Setup

Type of Insulin: 10/90 ▼

Profile Start Date: 11/09/97 ▲▼ Profile Start Date: 2:50 PM ▲▼

Time Block Name	Start Time	End Time	Pump Rate
Time Block #1	12:00 AM	12:29 AM	0.0
Time Block #2	12:30 AM	11:59 PM	0.0

[Insert] [Edit...] [Delete]

[OK] [Cancel] [Help]

Fig. 29

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0955718 011201

09/555718

PCT/US98/25850

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Accutivity Meter Setup Manager

X

Personal

Glucose Units/Ranges

Insulin Type

Event Markers

Time Block

Insulin Pump Profile

Misc Options

Language

Tip Messages

Select the appropriate Meter Customization Options

Decimal Format

☐ Comma [,]
 ☒ Period [.]

Time Format

☐ 24 Hour
 ☒ 12 Hour

Date Format

☐ dd-mm-yy
 ☒ mm-dd-yy

Meter Back Light

☐ Off
 ☒ On

Beeper

☐ Off
 ☒ On

OK

Cancel

Help

Fig. 30

Accutivity Meter Setup Manager

X

Personal

Glucose Units/Ranges

Insulin Type

Event Markers

Time Block

Insulin Pump Profile

Misc Options

Language

Tip Messages

Select four Languages for the Meter Setup.

Languages

☐ Dutch

☒ English

☒ French

☒ German

☐ Italian

☒ Spanish

☐ Swedish

OK

Cancel

Help

Fig. 31

Accutivity Meter Setup Manager X

Personal | Glucose Units/Ranges | Insulin Type | Event Markers
Time Block | Insulin Pump Profile | Misc Options | Language | Tip Messages

Select 10 Tip Messages to add to the Meter Setup from the list below.
To add Custom Tip Messages to the list below, select the 'Custom' button

☒ Tip Messages Enabled for Meter Setup

You have selected 10 Tip Messages.

S	C	Available Events	
✓		Check your feet daily	▲ ▼
✓		Choose a nutrition goal you can already do	
✓		Choose an exercise goal you can already do	
		Exercise helps keep your blood sugars in range	
✓		Exercise is important for good diabetes management	
✓		Exercise makes you more fit	
		Ketones provide you with important information	
		See your dentist every six months	
✓		See your diabetes educator regularly	
✓		See your doctor regularly	
✓		See your eye doctor annually	
✓		Tailor goals to fit your own lifestyle	

S = Selected Tip Messages Custom...

C = Custom Tip Messages

OK Cancel Help

Fig. 32

View Patient Report		X
Patient Name	Serial number	Received
John Smith	0005040225	
File Path: <input type="text"/>		<input type="button" value="View"/> <input type="button" value="Cancel"/> <input type="button" value="Browse..."/>
		<input type="button" value="Help"/>

Fig. 33

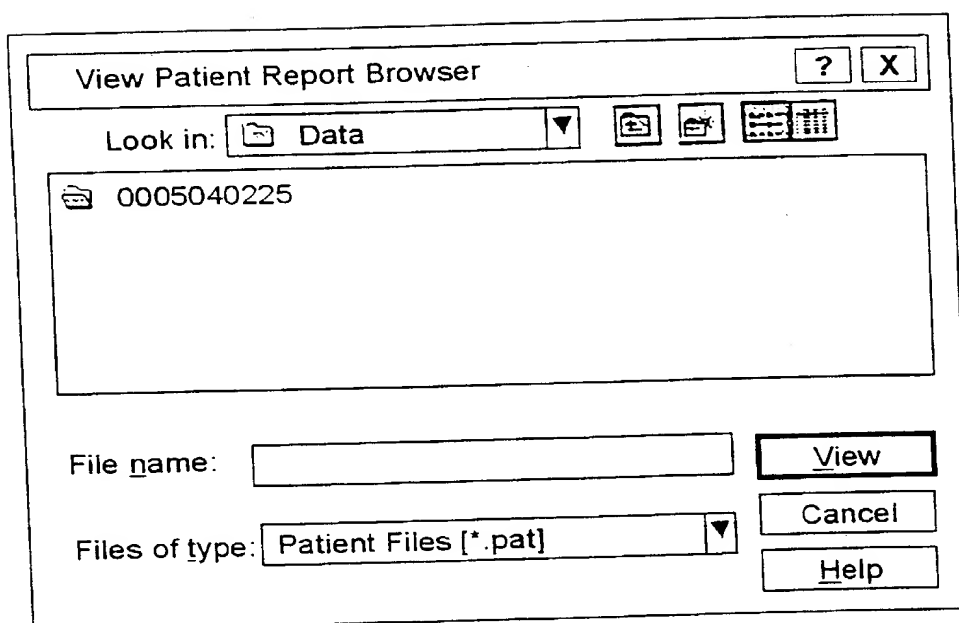
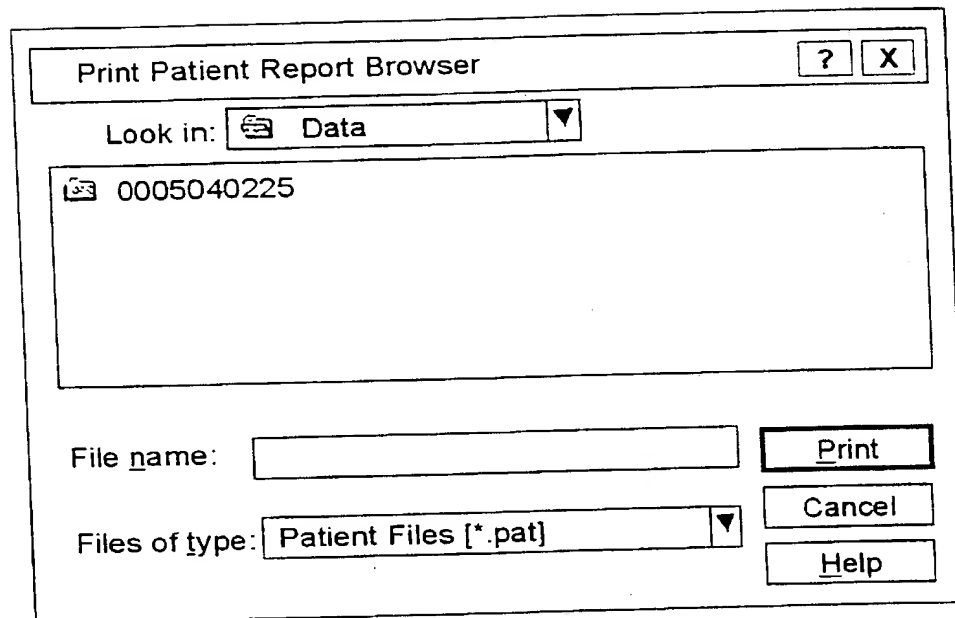


Fig. 34

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Fig. 35

*Fig. 36*

Patient Name	Serial number
tracy	1230123456

Buttons: Add..., Edit..., Remove, Close, Help

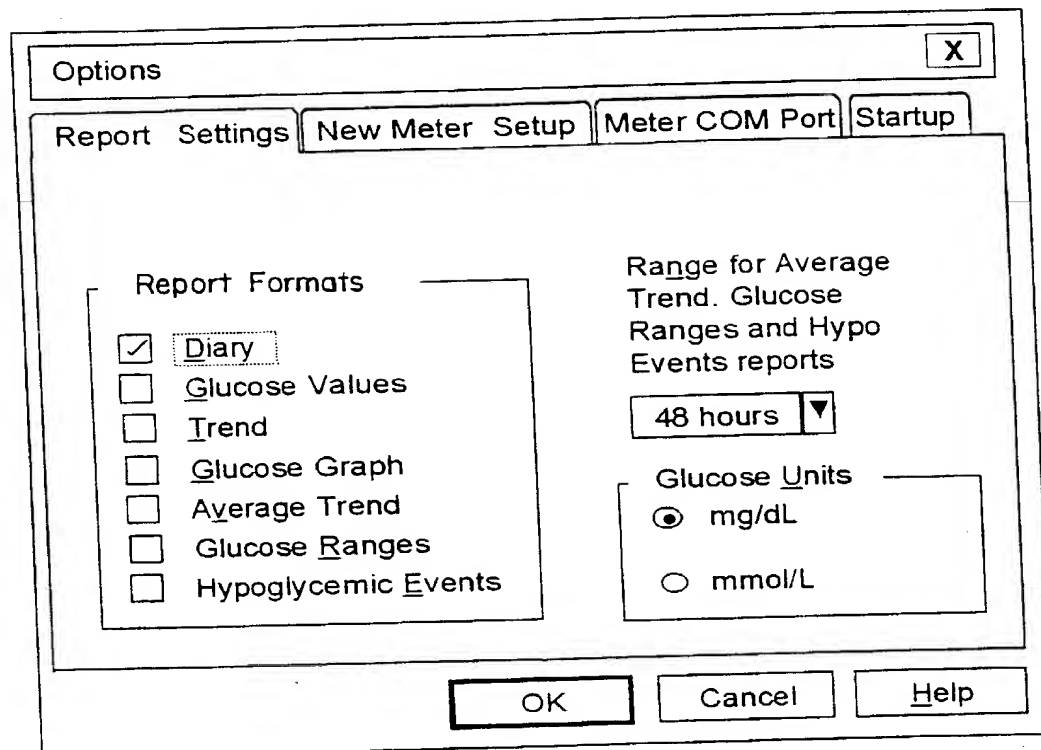
Fig. 37

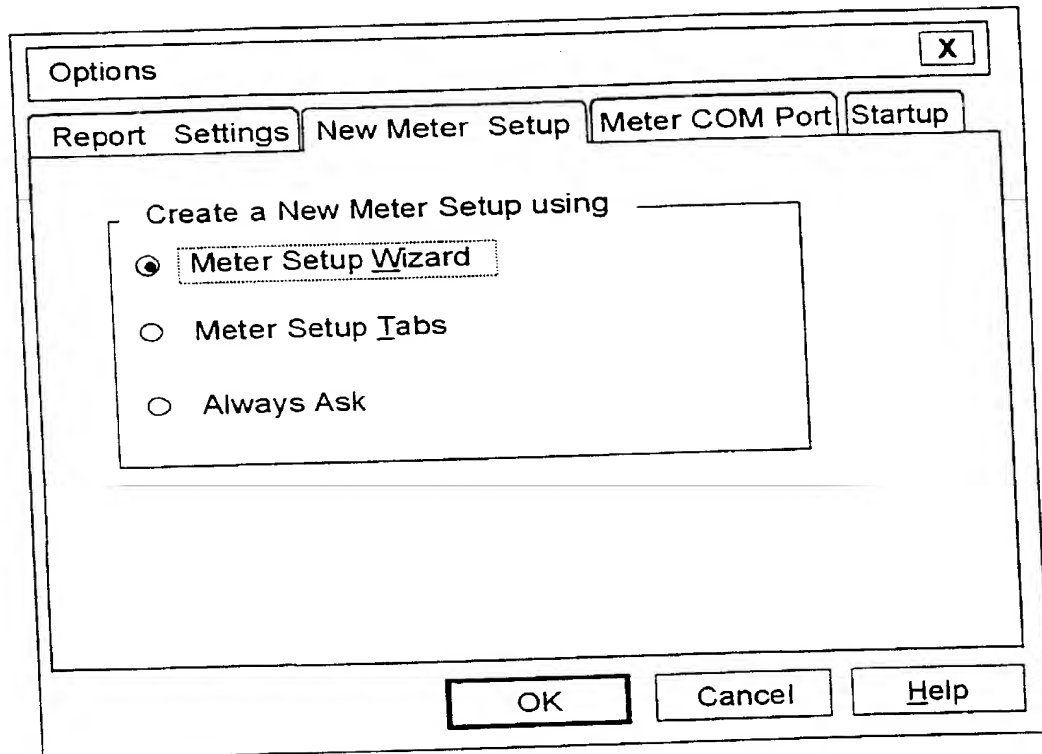
Patient Name:

Meter Serial Number:

Buttons: OK, Cancel, Help

Fig. 38

*Fig. 39*

*Fig. 40*

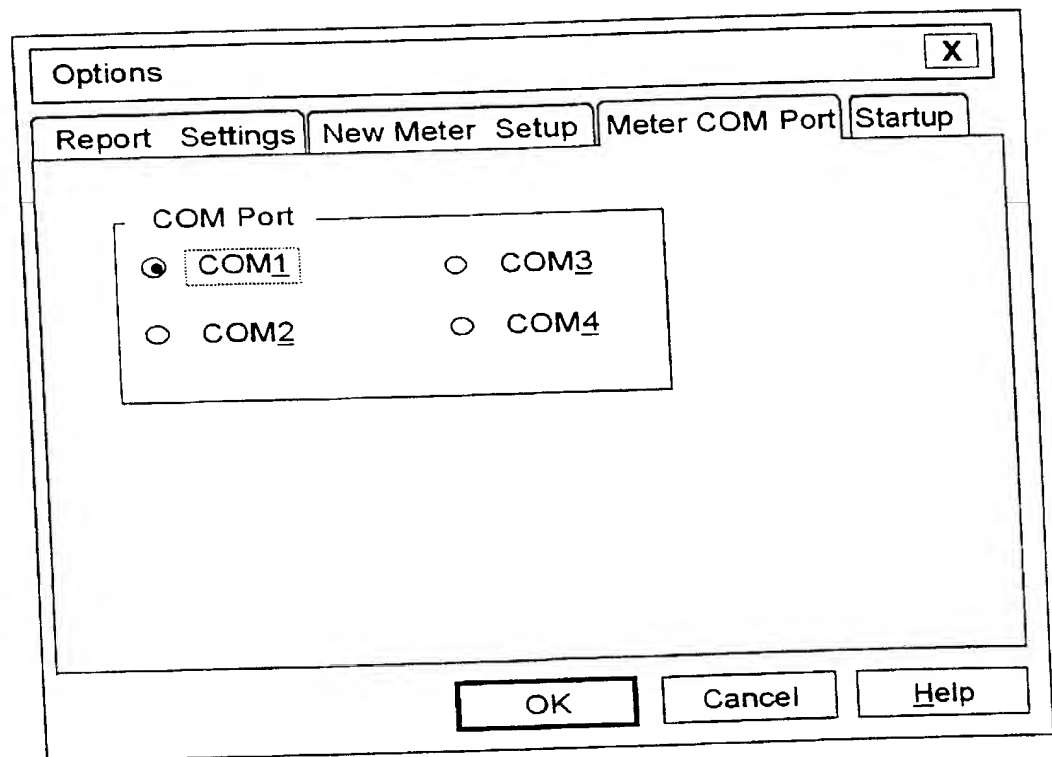


Fig. 41

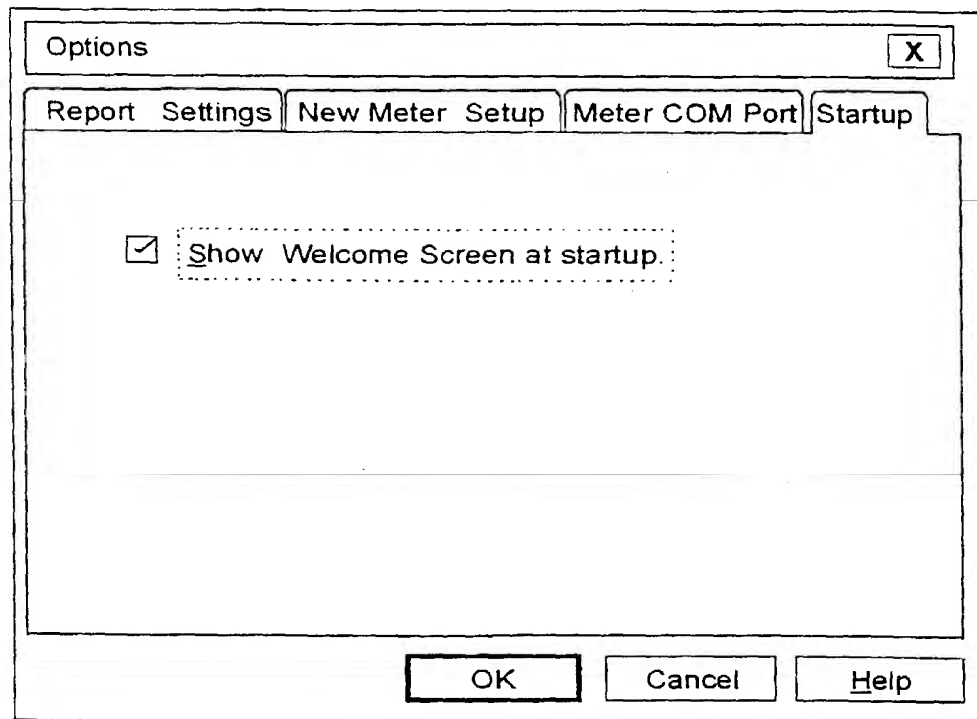


Fig. 42

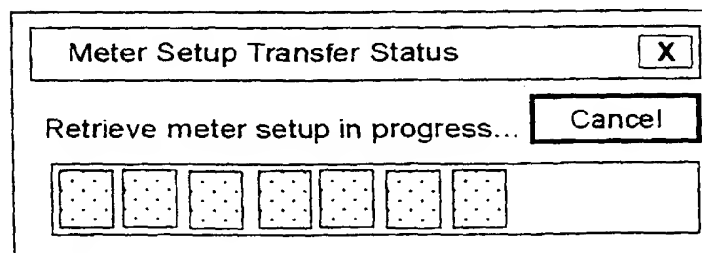


Fig. 43

WO 99/27849

09555718 011201

09/555718

PCT/US98/25850

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Enter Patient Name

X

The meter serial number has no corresponding patient name. Please enter the patient's name.

Meter Serial Number: 0005040225

Patient Name:

OK

Cancel

Help

Fig. 44

Meter Date and Time

X

Computer Settings

Date: 11/9/98
Time: 3:45 PM

Meter Settings

Date: 11/9/98
Time: 3:46 PM

Set Date and Time

☒ Do not change Meter Settings
☐ Synchronize Meter Settings with Computer Settings
☐ Set new Meter Date and Time:

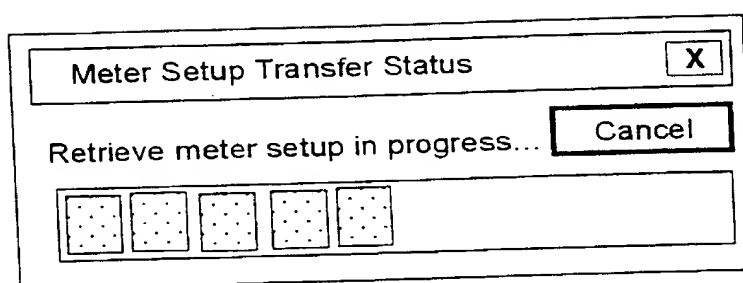
Date: 11/09/98
Time: 3:45 PM

OK

Cancel

Help

Fig. 45

*Fig. 46*

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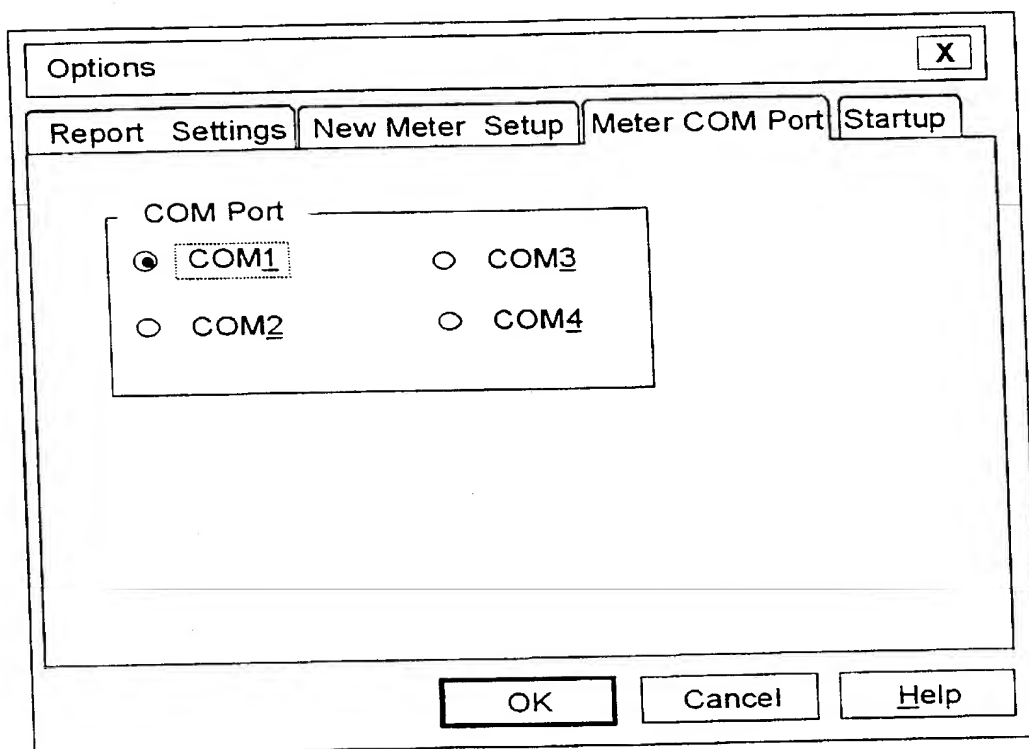
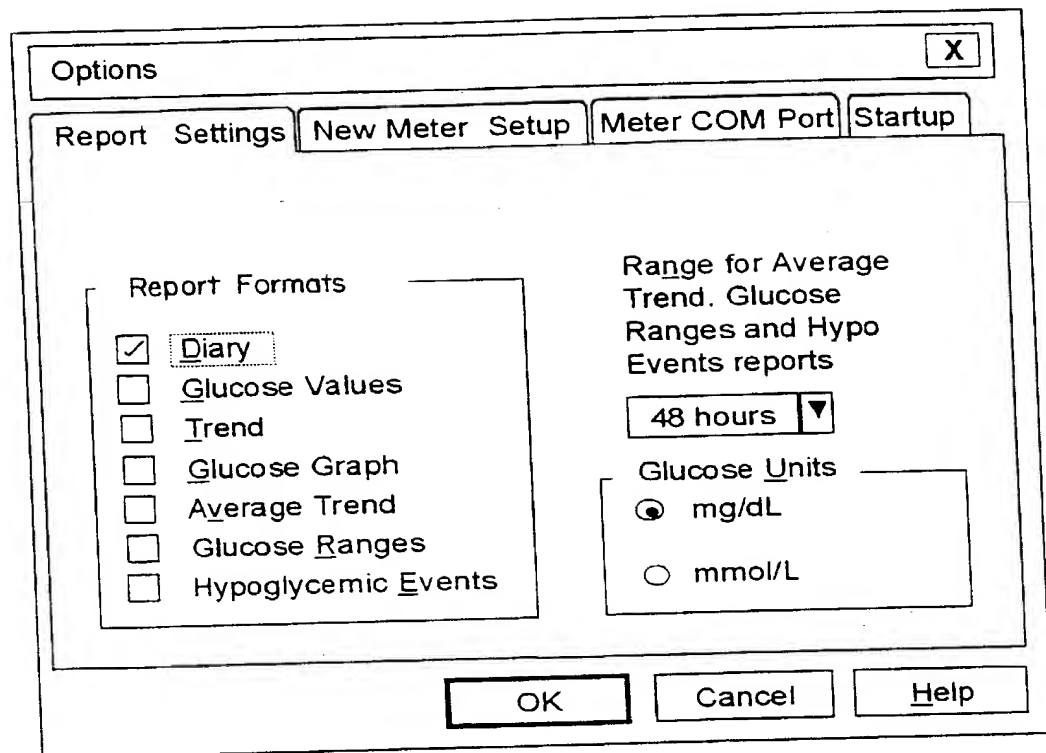


Fig. 47

*Fig. 48*

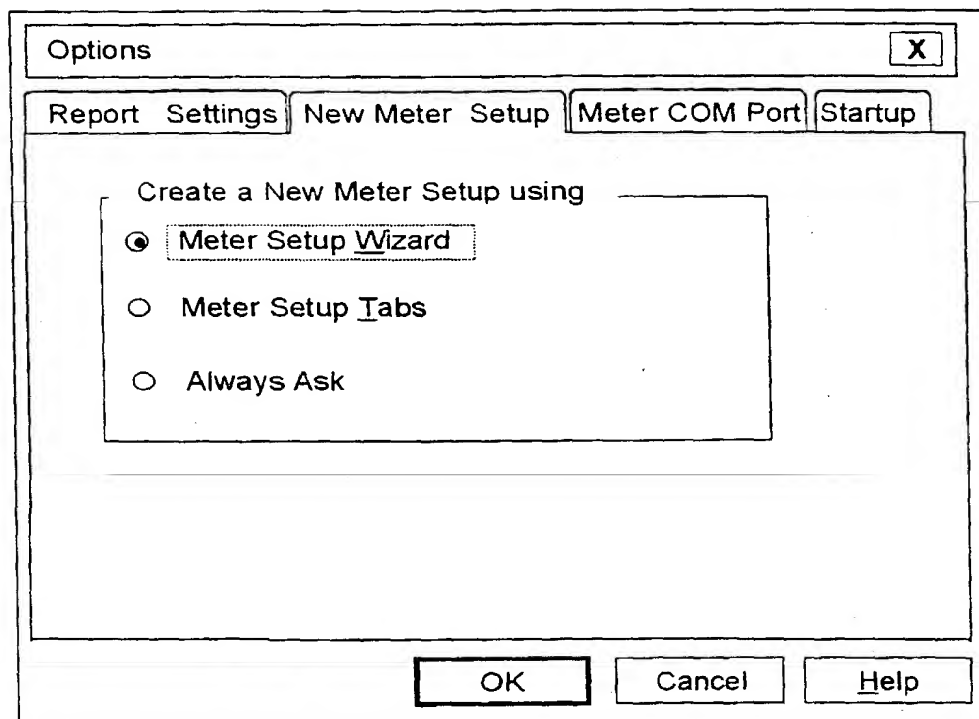


Fig. 49

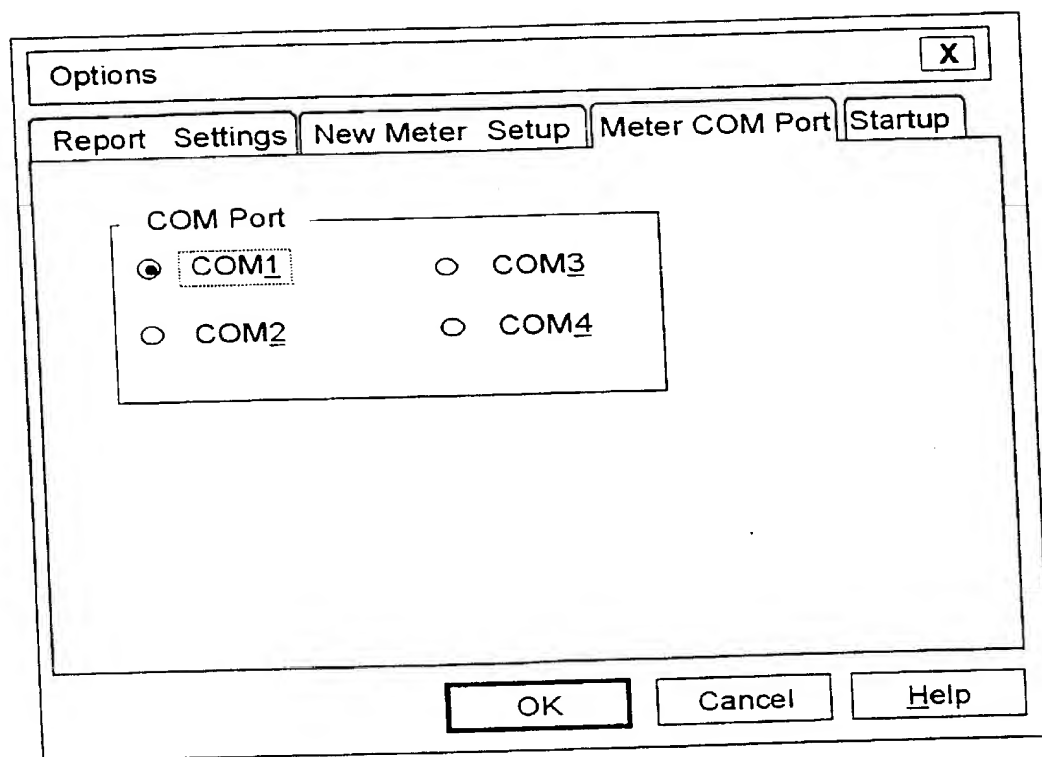


Fig. 50

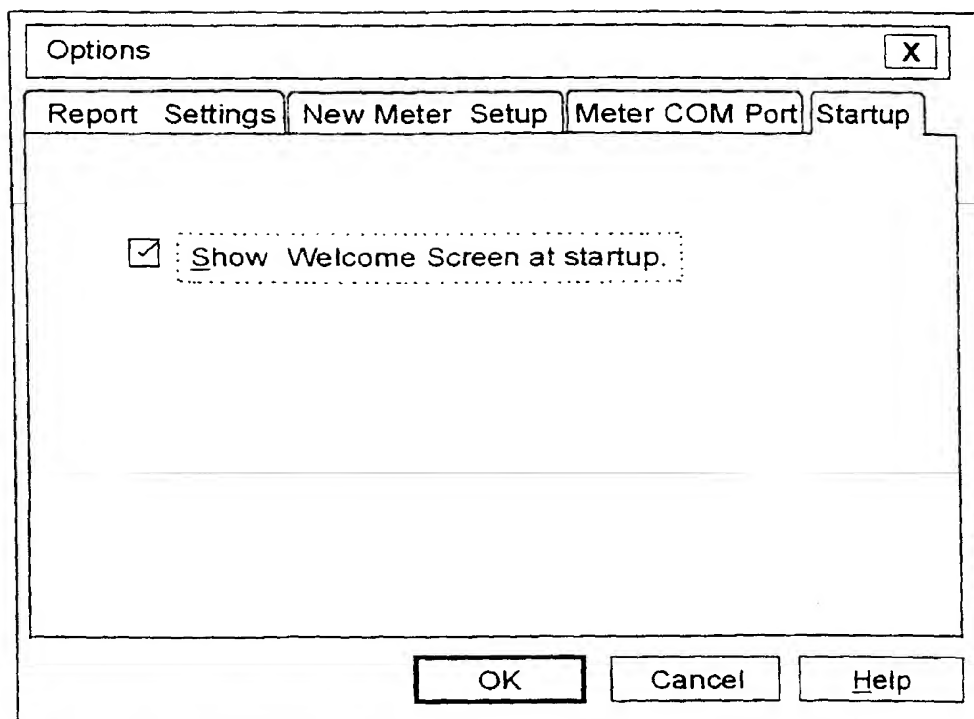


Fig. 51

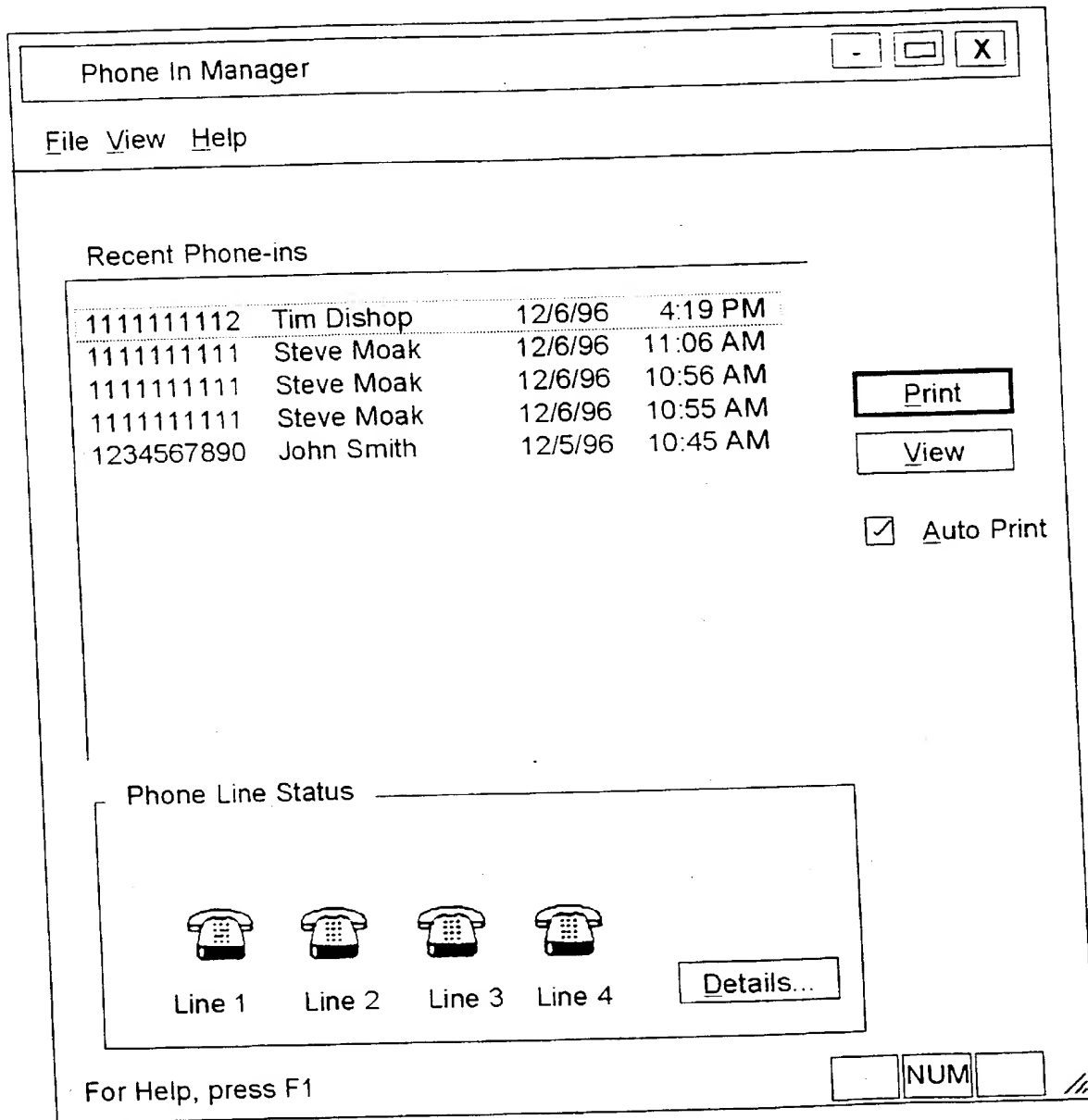


Fig. 52

WO 99/27849

09555718 .011201

09/555718
PCT/US98/25850

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-Patient Data Report

Close Print Settings... Help

Transfer Date/Time: 11/10/98 7:28 AM
Meter Serial Number: 0005040225
Patient Name: John Smith
Patient ID: default

Diary Report

Date	Time	Glucose (mg/dL)	Insulin Type	Insulin Dosage	Events	Other
1/16/98	7:30 AM	236	70/30	22.0	Before Meal	bG=high, Carbs=60g
1/16/98	12:28 PM	85			Before Meal	Carbs=60g
1/16/98	2:45 PM	179			After Meal	Carbs=30g
1/16/98	5:20 PM	314	Reg 70/30	2.0 8.0	Before Meal	bG=high, Carbs=60g
1/16/98	8:00 PM	250				bG=high
1/17/98	12:15 AM	275				bG=high
1/17/98	7:58 AM	151	70/30	22.0	Before Meal	Carbs=45g
1/17/98	10:00 AM	180			After Meal	Carbs=15g

Fig. 53

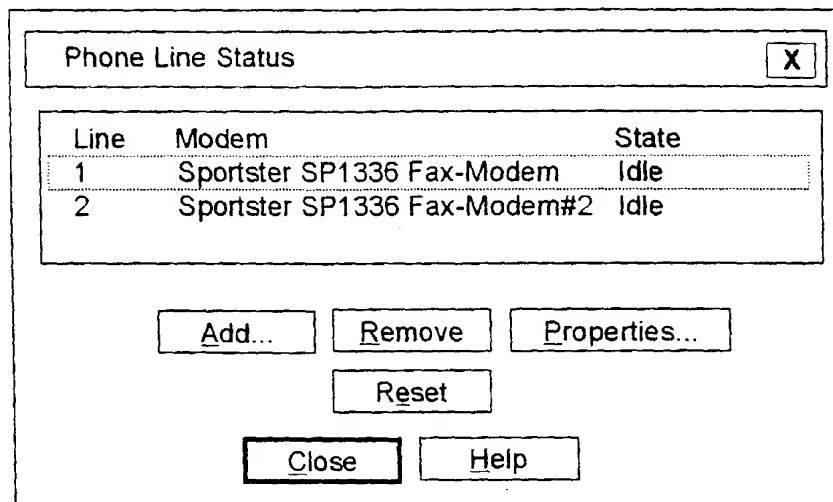
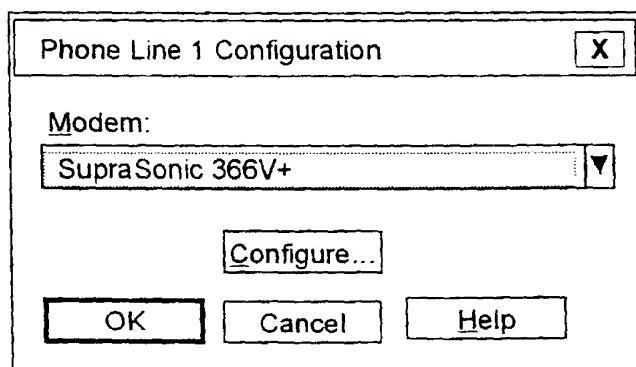
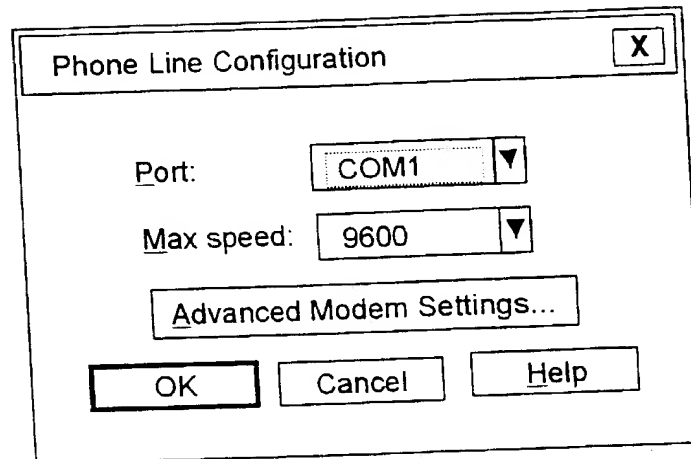
*Fig. 54**Fig. 55*

Fig. 56



Phone Line Configuration

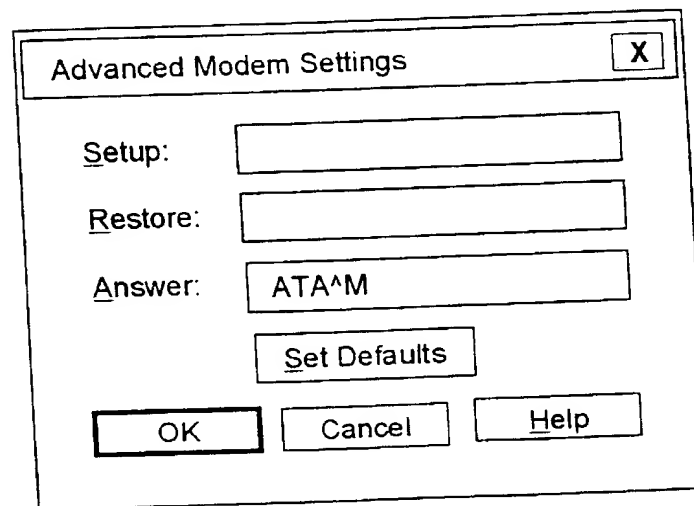
Port: COM1

Max speed: 9600

Advanced Modem Settings...

OK Cancel Help

Fig. 57



Advanced Modem Settings

Setup:

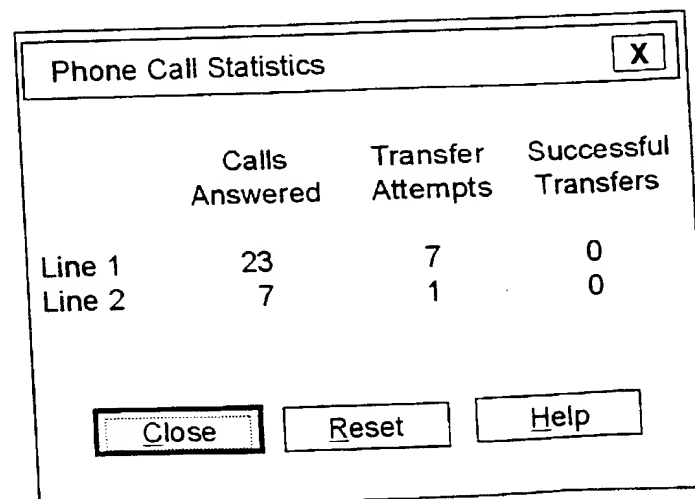
Restore:

Answer: ATA^M

Set Defaults

OK Cancel Help

Fig. 58

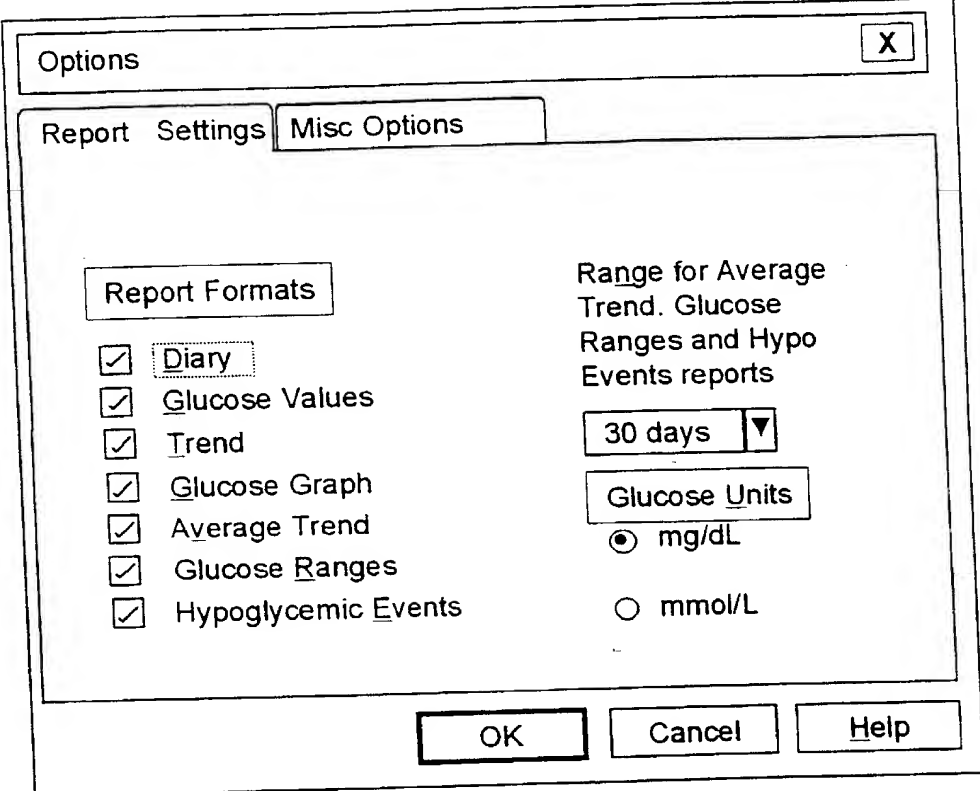


Phone Call Statistics

	Calls Answered	Transfer Attempts	Successful Transfers
Line 1	23	7	0
Line 2	7	1	0

Close Reset Help

Fig. 59



Options [X]

Report Settings Misc Options

Report Formats

- ☒ Diary
- ☒ Glucose Values
- ☒ Trend
- ☒ Glucose Graph
- ☒ Average Trend
- ☒ Glucose Ranges
- ☒ Hypoglycemic Events

Range for Average Trend. Glucose Ranges and Hypo Events reports

30 days ▼

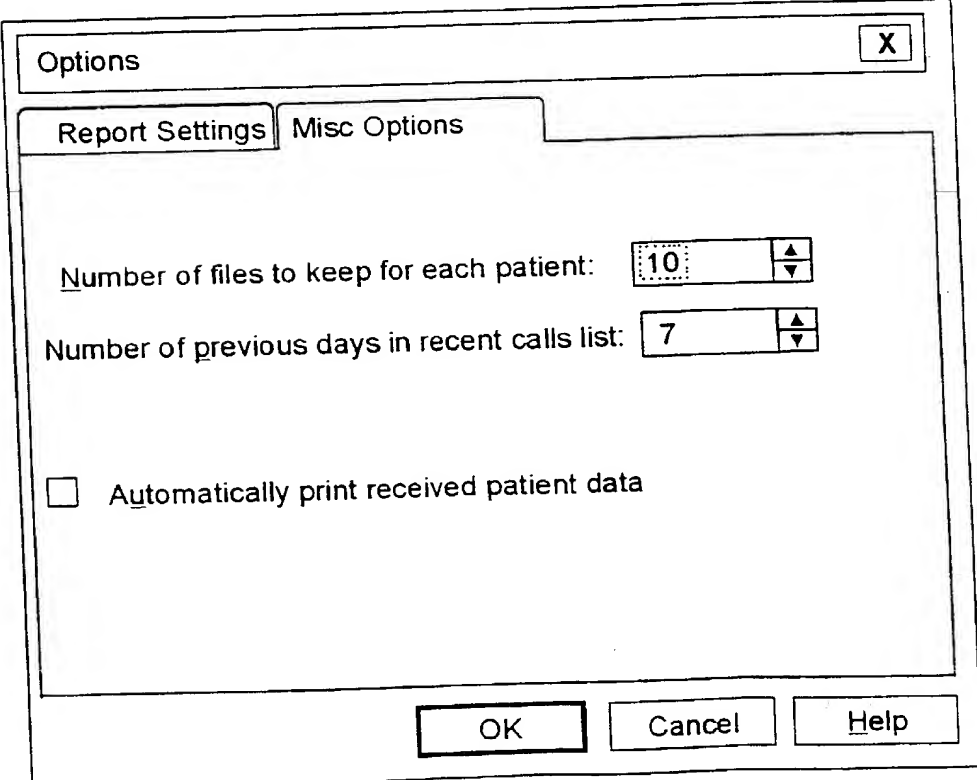
Glucose Units

☒ mg/dL

☐ mmol/L

OK Cancel Help

Fig. 60



Options [X]

Report Settings Misc Options

Number of files to keep for each patient: 10 ▲▼

Number of previous days in recent calls list: 7 ▲▼

☐ Automatically print received patient data

OK Cancel Help